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Date: March 7, 2008

To: Examiner Jeffrey S. Lundgren
U.S. Patent and Trademark Office
Group Art Unit 1639

Facsimile No.: 571-273-8300

From: Michael J. Belliveau, Ph.D.
Reg. No. 52,608

Re: U.S. Patent Application Serial No. 09/611,835
METHODS FOR IDENTIFYING COMBINATIONS OF ENTITIES AS THERAPEUTICS
Stockwell et al.
Filed July 7, 2000
Attorney Docket No. 50164/002002
Customer No. 21559
Confirmation No. 6924

Pages: 13, including cover page.

Message: The following papers are enclosed:

- Petition to Withdraw Notice of Abandonment and Issue Notice of Allowance (10 pages)
- Copy of Notice of Abandonment (2 pages)

PATENT
ATTORNEY DOCKET NO. 50164/002002

Certificate of Transmission by Facsimile: Date of Transmission: March 7, 2008

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being transmitted by facsimile to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, at facsimile number (571) 273-8300, on the date indicated above.

Rachel A. Kamerman
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Stockwell et al.	Confirmation No.:	6924
Serial No.:	09/611,835	Art Unit:	1639
Filed:	July 7, 2000	Examiner:	Jeffrey S. Lundgren
		Customer No.:	21559

Title: METHODS FOR IDENTIFYING COMBINATIONS OF ENTITIES AS THERAPEUTICS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO WITHDRAW NOTICE OF ABANDONMENT

AND ISSUE NOTICE OF ALLOWANCE

Under 37 C.F.R. § 1.181, applicants hereby petition to:

1. Have the Notice of Abandonment that was mailed in connection with the above-captioned case on February 11, 2008, a copy of which is enclosed, be withdrawn; and

2. Have a Notice of Allowance issued stating that claims 154-156 stand allowed, pursuant to the Decision on Rehearing of the Board of Patent Appeals and Interferences mailed November 20, 2007.

Summary of Applicants' Position

The Office erred in mailing a Notice of Abandonment, in view of the fact that the Board of Patent Appeals and Interferences ("the Board") withdrew the sole remaining ground of rejection of claims 154-156 in the Decision on Rehearing mailed November 20, 2007.

Where claims are found allowable by the Board, applicants need not file a reply to the Board Decision. Thus, there is no basis for the Office to have issued a Notice of Abandonment, and the Notice should be withdrawn. Furthermore, as provided by the M.P.E.P., an Examiner to whom a case has been transferred should give full faith and credit to the prior Examiner's search; should never regard a reversal by the Board as a challenge to make a new search to uncover other and better references; and should issue the application on the claims which stand allowed. Accordingly, the Office should issue a Notice of Allowance stating that claims 154-156 stand allowed.

Procedural Posture

Following an extensive examination process, applicants appealed to the Board from the final Office Action of March 21, 2005, in which claims 89-156 stood rejected under 35 U.S.C. § 103(a) as unpatentable over Stylli et al. (U.S.P.N. 5,985,214; "Stylli"). Applicants simultaneously filed a Pre-Appeal Brief Request for Review. The rejection under § 103(a) was maintained in the Pre-Appeal Brief Review; accordingly, applicants filed an Appeal Brief seeking reversal of the rejection. In its Decision on Appeal, the

Board reversed the Examiner in full, but set forth new grounds of rejection of claims 89-156 under § 103(a). Applicants then filed a Request for Rehearing seeking, *inter alia*, withdrawal of the Board's new ground of rejection of claims 154-156. The Board granted the Request for Rehearing with respect to claims 154-156, withdrawing its new ground of rejection of these claims while maintaining its rejection of the remaining claims.

On February 5, 2008, Examiner Lundgren telephoned applicants' representative, who confirmed that applicants did not intend to appeal from the Board Decision on Rehearing. On February 11, 2008, to applicants' surprise, the Examiner mailed a Notice of Abandonment, asserting that the application was abandoned in view of "Applicant's failure to timely file a proper reply to the Office letter mailed on 20 November 2007."

Applicants' representative conducted telephonic interviews with Examiner Lundgren regarding the Notice of Abandonment on February 27, 2008 and March 4, 2008. To date, the Notice of Abandonment has not been withdrawn. Accordingly, in an abundance of caution, applicants file the present Petition seeking withdrawal of the improper Notice of Abandonment and issuance of a Notice of Allowance for claims 154-156.

The Office Erred in Mailing a Notice of Abandonment

In the Decision on Appeal mailed April 20, 2007, the Board reversed the Examiner in full. The Board set forth new grounds of rejection of all claims under 35 U.S.C. § 103(a), pursuant to 37 C.F.R. § 41.50(b); upon reconsideration, the Board withdrew its

rejection of claims 154-156 (Decision on Rehearing, mailed November 20, 2007). Thus, following the Decision on Rehearing, **claims 154-156 were free of all rejections and objections, i.e., were allowable.**

Subsequent procedure is governed by 37 C.F.R. § 1.197(b) and M.P.E.P. §§ 1214.04 and 1214.06. 37 C.F.R. § 1.197(b) provides (emphasis added):

> (1) Proceedings on an application are considered terminated by the dismissal of an appeal or the failure to timely file an appeal to the court or a civil action (§ 1.304) **except:**
> (i) **Where claims stand allowed in an application**...

M.P.E.P. § 1214.04 states (emphasis added):

> A complete reversal of the examiner's rejection brings the case up for immediate action by the examiner. If the reversal does not place an application in condition for immediate allowance (e.g., the Board has entered a new ground of rejection under 37 CFR *>41.50(b)<), **the examiner should refer to the situations outlined in MPEP § 1214.06 for appropriate guidance.**

In turn, M.P.E.P. § 1214.06 states (emphasis added):

> Examiners must be very careful that case files that come back from the Board are not overlooked because **every case, except applications in which all claims stand rejected after the Board's decision, is up for action by the examiner in the event no court review has been sought**...
>
> II. CLAIMS STAND ALLOWED
> **The appellant is not required to file a reply.**

As noted above, claims 154-156 are allowable in the present case, as the Examiner was reversed in full by the Board, and the Board then withdrew its own rejection of these claims. Accordingly, pursuant to M.P.E.P. § 1214.06, applicants are not required to file a reply; rather, the case is up for action by the Examiner, as no court review has been sought.

In the Notice of Abandonment mailed February 11, 2008, the Examiner asserted that the application was abandoned in view of "Applicant's failure to timely file a proper reply to the Office letter mailed on 20 November 2007[,]" i.e., the Decision on Rehearing. As provided by 37 C.F.R. § 1.197(b) and M.P.E.P. §§ 1214.04 and 1214.06, there was no requirement for applicants either to appeal from or reply to the favorable Decision on Rehearing. Accordingly, the Notice of Abandonment is without merit, and applicants respectfully request that it be withdrawn.

The Office Should Issue a Notice of Allowance for Claims 154-156

When, as here, the Board reverses or withdraws all rejections of particular claims, subsequent procedure is governed by M.P.E.P. §§ 1214.04 and 1214.06. M.P.E.P. § 1214.04 states (emphasis added):

> The examiner should never regard [] a reversal [by the Board] as a challenge to make a new search to uncover other and better references. This is particularly so where the application or *ex parte* reexamination proceeding has meanwhile been transferred or assigned to an examiner other than the one who rejected the claims leading to the appeal. **The second examiner should give full faith and credit to the prior examiner's search.**
>
> If the examiner has **specific knowledge** of the existence of a particular reference or references which indicate nonpatentability of any of the appealed claims as to which the examiner was reversed, he or she should submit the matter to the Technology Center (TC) Director for authorization to reopen prosecution under 37 CFR 1.198 for the purpose of entering the new rejection.

In the present case, the Examiner of record prior to and during the Appeal process was Examiner Tran; see, e.g., the final Office Action mailed March 21, 2005, the Notice of Panel Decision from Pre-Appeal Brief Review mailed October 19, 2005, and the

Examiner's Answer mailed June 15, 2006. The present Examiner of record is Examiner Lundgren. Pursuant to M.P.E.P. § 1214.04, as cited above, the present Examiner is to give full faith and credit to Examiner Tran's previous searches and examination of the case. All issues, aside from the obviousness rejection over Stylli, had been resolved before Examiner Tran and her predecessors, in the course of a thorough examination process that included seven Office Actions. As to the remaining rejection, the Board reversed Examiner Tran in full, and upon reconsideration, withdrew its own rejection of claims 154-156. The status of claims 154-156 is now clear: They are allowable.

In the two telephonic interviews conducted with Examiner Lundgren and applicants' representative since receiving the Notice of Abandonment, Examiner Lundgren indicated no "specific knowledge of the existence of a particular reference or references which indicate nonpatentability of any of the appealed claims as to which the examiner was reversed." Accordingly, pursuant to the policy articulated in M.P.E.P. § 1214.04, it would not be appropriate for the Office to embark on a "new search to uncover other and better references," particularly in the present context of a thoroughgoing prior examination process conducted by a different examiner. Instead, the pronouncement of the Board should be adhered to, and a Notice of Allowance should be issued for claims 154-156.

To provide further support for applicants' position, applicants again direct the Office's attention to M.P.E.P. § 1214.06, which states (emphasis added):

> II. CLAIMS STAND ALLOWED
> The appellant is not required to file a reply. **The examiner issues the application or *ex parte* reexamination certificate on the claims which stand allowed...**
>
> If the Board affirms a rejection of claim 1, claim 2 was objected to prior to appeal as being allowable except for its dependency from claim 1 and independent claim 3 is allowed, the examiner should cancel claims 1 and 2 and issue the application or *ex parte* reexamination certificate with claim 3 only...
>
> IV. 37 CFR *>41.50(b)< REJECTION
> Where the Board makes a new rejection under 37 CFR *>41.50(b)< and no action is taken with reference thereto by appellant within 2 months, **the examiner should proceed in the manner indicated in paragraphs I-III of this section as appropriate.**

In the above-cited example, the rejection of claim 1 is affirmed, claim 2 is objected to, and claim 3 is allowed. In such a case, the Examiner should issue the application with claim 3 and cancel the other claims. Likewise, here, the Examiner should issue the application with allowed claims 154-156, while cancelling the remaining claims. As M.P.E.P. § 1214.06.IV indicates, the existence of a Board rejection under 37 C.F.R. § 41.50(b) of the remaining claims should not change the procedure followed by the Examiner; rather, "the examiner should proceed in the manner indicated in paragraphs I-III of this section as appropriate[,]" i.e., paragraph II in the present case.

As a final matter, while further search or examination of claims 154-156 is inappropriate for the reasons articulated above, applicants reproduce, for the Office's convenience, the passage from applicants' Request for Rehearing filed June 20, 2007 (pages 3-5) that addressed claims 154-156 and ultimately persuaded the Board to withdraw its new rejection of these claims:

Claims 154-156

Claim 154-156 are directed to appellants' so-called "rank order" screening method. In this method, which is described in the specification on page 6, lines 21-27, through page 7, lines 1-6, before combinations are tested, at least 100 compounds are tested individually for activity against test cells. Compounds that demonstrate activity individually are then tested as large numbers of combinations. For the Board's convenience, claim 154 is reproduced below.

154. A method of discovering a desired two or higher order combination of compounds having the ability to affect a biological property of living cells in a way that is indicative of the potential for therapeutic efficacy in an animal, said method comprising the steps of:
(a) contacting living test cells with at least 100 compounds under conditions that ensure that each compound/test cell contacting is segregated from the others,
(b) detecting or measuring a biological property of said test cells,
(c) selecting compounds that cause a change in said biological property relative to said biological property of said test cells not contacted with said compounds,
(d) contacting at least 49 unique two or higher order combinations of the selected compounds of step (c) with living test cells under conditions that ensure that each contacting is segregated from the others,
(e) detecting or measuring a biological property of said test cells of step (d), and
(f) identifying combinations of compounds that cause an effect on said biological property of said test cells that is different from the effect of each compound of the combination by itself, wherein said identified combinations of compounds have potential therapeutic use in an animal.

The Board contends that the method of claims 154-156 is unpatentable as being obvious over Stylli in view of West, Burgin, and Chiang. In its reasons supporting the rejection of claims 154-156, the Board makes no mention of the requirement in these claims that compounds be tested individually before being tested in combination. Indeed, the Board appears to overlook the fact that steps (a)-(d) of claim 154 are very different from steps (a)-(d) of the other independent claims: the Board states that Stylli "meets the limitations of steps (a) through (d) of independent claims 89, 114, 135, 149, and 154, and dependent claim 156." There is no explanation in the Board's decision for the Board's assertion that Stylli teaches these steps. No could there be; there is nothing in Stylli teaching or suggesting the claimed screening method. Moreover, nothing in the references newly cited by the Board remedies the

> deficiencies of Stylli. West, Burgin, and Chiang each teaches a method that employs pooling of agents. Pooling is employed by researchers such as West, Burgin and Chiang in order to improve screening efficiency by eliminating the requirement that each compound be tested individually. For example, in the method described by West at column 11, lines 9-40, and relied upon by the Board, pools of one thousand [potential] inhibitors are screened in wells. If a well is found to contain an inhibitor, "then the pool can be subdivided into 10 pools of 100 and the process repeated until an individual inhibitor is identified." (col. 11, ll. 46-48). Thus, using the method described by West and beginning with 10 panels of one thousand compounds, a practitioner would need test only 10 compounds individually.[1] In stark contrast, one employing the method of claim 154 would first test every compound individually to identify those that change a particular biological property. Importantly, compounds so identified are then combined after their individual activity has been discovered, a step that West and Burgin, searching for individual compounds having biological activity, do not suggest performing.
>
> Because none of the references cited by the Board teach or suggest testing compounds individually and then testing them in combination, appellants respectfully request that the rejection of claims 154-156 as being obvious be withdrawn.

The Board has accepted the above arguments and has withdrawn its rejection of claims 154-156. These claims are now free of all rejections and objections, and are therefore allowable. Further search and examination at this stage, after nearly eight years of prosecution and a clear pronouncement by the Board, would be inconsistent with Office rules and policy. Accordingly, applicants respectfully request issuance of a Notice of Allowance for claims 154-156.

[1] The teachings of Burgin and Chiang are similar to those of West, and provide no support for the Board's position that claims 154-156 are unpatentable as being obvious. [Footnote in original]

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 3/7/08

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/611,835	07/07/2000	Brent R. Stockwell	50164/002002	6924

21559 7590 02/11/2008

CLARK & ELBING LLP
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EXAMINER	
LUNDGREN, JEFFREY S	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
02/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

CENTRAL FAX CENTER

MAR 07 2008

COPY

Notice of Abandonment	Application No. 09/611,835	Applicant(s) STOCKWELL ET AL.
	Examiner Jeff Lundgren	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *20 November 2007*
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee), or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114)
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111 (See explanation in box 7 below).
   (d) ☒ No reply has been received

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims

7. ☒ The reason(s) below.

Mr. Belliveau confirmed that no reply has been filed in the instant application.

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.